PRIA Fee Category Table – Antimicrobials Division – New Products and Amendments

Table 9.

EPA No.	New CR No.	Action	Decision Review Time (Months)[HYPERLINK "http://www2.epa.gov/pria-fees/pria-fee-category-table-antimicrobial-division-new-products-and-amendments" \l "footnote1"]	FY'17 & FY'18 Registration Service Fee ($)
[HYPERLINK "http://www2.epa.gov/pria-fees/a530-pria-fee-category"]	81	New product, identical or substantially similar in composition and use to a registered product; no data review or only product chemistry data; cite all data citation or selective data citation where applicant owns all required data; or applicant submits specific authorization letter from data owner. Category also includes 100% re-package of registered end-use or manufacturing use product that requires no data submission nor data matrix. [HYPERLINK "http://www2.epa.gov/pria-fees/pria-fee-category-table-antimicrobial-division-new-products-and-amendments" \l "footnote2"] [HYPERLINK "http://www2.epa.gov/pria-fees/pria-fee-category-table-	4	1,278

EPA No.	New CR No.	Action	Decision Review Time (Months)[HYPERLINK "http://www2.epa.gov/pria-fees/pria-fee-category-table-antimicrobial-division-new-products-and-amendments" \l "footnote1"]	FY'17 & FY'18 Registration Service Fee ($)
		antimicrobial-division-new-products-and-amendments" \l "footnote3"]		
[HYPERLINK "http://www2.epa.gov/pria-fees/a531-pria-fee-category"]	82	New product; identical or substantially similar in composition and use to a registered product; registered source of active ingredient: selective data citation only for data on product chemistry and/or acute toxicity and/or public health pest efficacy, where applicant does not own all required data and does not have a specific authorization letter from data owner. [HYPERLINK "http://www2.epa.gov/pria-fees/pria-fee-category-table-antimicrobial-division-new-products-and-amendments" \l "footnote2"] [HYPERLINK "http://www2.epa.gov/pria-fees/pria-fee-category-table-antimicrobial-division-new-products-and-amendments" \l "footnote3"]	4	1,824
[HYPERLINK "http://www2.epa.gov/	83	New product; identical or substantially similar	5	5,107

EPA No.	New CR No.	Action	Decision Review Time (Months)[HYPERLINK "http://www2.epa.gov/pria-fees/pria-fee-category-table-antimicrobial-division-new-products-and-amendments" \l "footnote1"]	FY'17 & FY'18 Registration Service Fee ($)
pria-fees/a532-pria-fee-category"]		in composition and use to a registered product; registered active ingredient; unregistered source of active ingredient; cite-all data citation except for product chemistry; product chemistry data submitted [HYPERLINK "http://www2.epa.gov/pria-fees/pria-fee-category-table-antimicrobial-division-new-products-and-amendments" \l "footnote2"] [HYPERLINK "http://www2.epa.gov/pria-fees/pria-fee-category-table-antimicrobial-division-new-products-and-amendments" \l "footnote3"]		
[HYPERLINK "http://www2.epa.gov/pria-fees/a540-pria-fee-category"]	84	New end use product; FIFRA §2(mm) uses only; up to 25 public health organisms [HYPERLINK "http://www2.epa.gov/pria-fees/pria-fee-category-table-antimicrobial-division-new-products-and-amendments" \l "footnote2"] [HYPERLINK "http://www2.epa.gov/	5	5,107

EPA No.	New CR No.	Action	Decision Review Time (Months)[HYPERLINK "http://www2.epa.gov/pria-fees/pria-fee-category-table-antimicrobial-division-new-products-and-amendments" \l "footnote1"]	FY'17 & FY'18 Registration Service Fee ($)
		pria-fees/pria-fee-category-table-antimicrobial-division-new-products-and-amendments" \l "footnote3"] [HYPERLINK "http://www2.epa.gov/pria-fees/pria-fee-category-table-antimicrobial-division-new-products-and-amendments" \l "footnote3"] (6)		
A541	85 (new)	New end use product; FIFRA §2(mm) uses only; 26-50 public health organisms [HYPERLINK "http://www2.epa.gov/pria-fees/pria-fee-category-table-antimicrobial-division-new-products-and-amendments" \l "footnote2"] [HYPERLINK "http://www2.epa.gov/pria-fees/pria-fee-category-table-antimicrobial-division-new-products-and-amendments" \l "footnote3"] [HYPERLINK "http://www2.epa.gov/pria-fees/pria-fee-category-table-antimicrobial-division-new-products-and-	7	8,500

EPA No.	New CR No.	Action	Decision Review Time (Months)[HYPERLINK "http://www2.epa.gov/pria-fees/pria-fee-category-table-antimicrobial-division-new-products-and-amendments" \l "footnote1"]	FY'17 & FY'18 Registration Service Fee ($)
		amendments" \l "footnote3"][6]		
A542	86 (new)	New end use product; FIFRA §2(mm) uses only; ≥ 51 public health organisms [HYPERLINK "http://www2.epa.gov/pria-fees/pria-fee-category-table-antimicrobial-division-new-products-and-amendments" \l "footnote2"] [HYPERLINK "http://www2.epa.gov/pria-fees/pria-fee-category-table-antimicrobial-division-new-products-and-amendments" \l "footnote3"] [HYPERLINK "http://www2.epa.gov/pria-fees/pria-fee-category-table-antimicrobial-division-new-products-and-amendments" \l "footnote3"]	10	15,000
[HYPERLINK "http://www2.epa.gov/pria-fees/a550-pria-fee-category"]	87	New end-use product; uses other than FIFRA §2(mm); non-FQPA product [HYPERLINK "http://www2.epa.gov/pria-fees/pria-fee-category-table-antimicrobial-division-new-products-and-	9	13,226

EPA No.	New CR No.	Action	Decision Review Time (Months)[HYPERLINK "http://www2.epa.gov/pria-fees/pria-fee-category-table-antimicrobial-division-new-products-and-amendments" \l "footnote1"]	FY'17 & FY'18 Registration Service Fee ($)
		amendments" \l "footnote2"] [HYPERLINK "http://www2.epa.gov/pria-fees/pria-fee-category-table-antimicrobial-division-new-products-and-amendments" \l "footnote3"] [HYPERLINK "http://www2.epa.gov/pria-fees/pria-fee-category-table-antimicrobial-division-new-products-and-amendments" \l "footnote3"]		
[HYPERLINK "http://www2.epa.gov/pria-fees/a560-pria-fee-category"]	88	New manufacturing use product; registered active ingredient; selective data citation [HYPERLINK "http://www2.epa.gov/pria-fees/pria-fee-category-table-antimicrobial-division-new-products-and-amendments" \l "footnote2"] [HYPERLINK "http://www2.epa.gov/pria-fees/pria-fee-category-table-antimicrobial-division-new-products-and-amendments" \l "footnote3"]	6	12,596

EPA No.	New CR No.	Action	Decision Review Time (Months)[HYPERLINK "http://www2.epa.gov/pria-fees/pria-fee-category-table-antimicrobial-division-new-products-and-amendments" \l "footnote1"]	FY'17 & FY'18 Registration Service Fee ($)
A565	89 (new)	New manufacturing-use product; registered active ingredient; unregistered source of active ingredient; submission of new generic data package; registered uses only; requires science review (2) (3)	12	18,234
[HYPERLINK "http://www2.epa.gov/pria-fees/a570-pria-fee-category"]	90	Label amendment requiring data review; up to 25 public health organisms [HYPERLINK "http://www2.epa.gov/pria-fees/pria-fee-category-table-antimicrobial-division-new-products-and-amendments" \l "footnote3"] [HYPERLINK "http://www2.epa.gov/pria-fees/pria-fee-category-table-antimicrobial-division-new-products-and-amendments" \l "footnote4"] [HYPERLINK "http://www2.epa.gov/pria-fees/pria-fee-category-table-antimicrobial-division-new-products-and-amendments" \l "footnote3"] (6)	4	3,831

EPA No.	New CR No.	Action	Decision Review Time (Months)[HYPERLINK "http://www2.epa.gov/pria-fees/pria-fee-category-table-antimicrobial-division-new-products-and-amendments" \l "footnote1"]	FY'17 & FY'18 Registration Service Fee ($)
A573	91 (new)	Label amendment requiring data review; 26-50 public health organisms [HYPERLINK "http://www2.epa.gov/pria-fees/pria-fee-category-table-antimicrobial-division-new-products-and-amendments" \l "footnote2"] [HYPERLINK "http://www2.epa.gov/pria-fees/pria-fee-category-table-antimicrobial-division-new-products-and-amendments" \l "footnote3"] [HYPERLINK "http://www2.epa.gov/pria-fees/pria-fee-category-table-antimicrobial-division-new-products-and-amendments" \l "footnote3"](7)	6	6,350
A574	92 (new)	Label amendment requiring data review; ≥ 51 public health organisms [HYPERLINK "http://www2.epa.gov/pria-fees/pria-fee-category-table-antimicrobial-division-new-products-and-amendments" \l "footnote2"] [HYPERLINK "http://www2.epa.gov/	9	11,000

EPA No.	New CR No.	Action	Decision Review Time (Months)[HYPERLINK "http://www2.epa.gov/pria-fees/pria-fee-category-table-antimicrobial-division-new-products-and-amendments" \l "footnote1"]	FY'17 & FY'18 Registration Service Fee ($)
		pria-fees/pria-fee-category-table-antimicrobial-division-new-products-and-amendments" \l "footnote3"] [HYPERLINK "http://www2.epa.gov/pria-fees/pria-fee-category-table-antimicrobial-division-new-products-and-amendments" \l "footnote3"] (7)		
[HYPERLINK "http://www2.epa.gov/pria-fees/a572-pria-fee-category"]	93	New Product or amendment requiring data review for risk assessment by Science Branch (e.g., changes to REI, or PPE, or use rate) [HYPERLINK "http://www2.epa.gov/pria-fees/pria-fee-category-table-antimicrobial-division-new-products-and-amendments" \l "footnote2"] [HYPERLINK "http://www2.epa.gov/pria-fees/pria-fee-category-table-antimicrobial-division-new-products-and-amendments" \l "footnote3"] [HYPERLINK "http://www2.epa.gov/pria-fees/pria-fee-category-table-	9	13,226

EPA No.	New CR No.	Action	Decision Review Time (Months)[HYPERLINK "http://www2.epa.gov/pria-fees/pria-fee-category-table-antimicrobial-division-new-products-and-amendments" \l "footnote1"]	FY'17 & FY'18 Registration Service Fee ($)
		antimicrobial-division-new-products-and-amendments" \l "footnote4"]		

[1]A decision review time that would otherwise end on a Saturday, Sunday, or federal holiday, will be extended to end on the next business day.

[2]An application for a new end-use product using a source of active ingredient that (a) is not yet registered but (b) has an application pending with the Agency for review, will be considered an application for a new product with an unregistered source of active ingredient.

[3]Where the action involves approval of a new or amended label, on or before the end date of the decision review time, the Agency shall provide to the applicant a draft accepted label, including any changes made by the Agency that differ from the applicant-submitted label and relevant supporting data reviewed by the Agency. The applicant will notify the Agency that the applicant either (a) agrees to all of the terms associated with the draft accepted label as amended by the Agency and requests that it be issued as the accepted final Agency-stamped label; or (b) does not agree to one or more of the terms of the draft accepted label as amended by the Agency and requests additional time to resolve the difference(s); or (c) withdraws the application without prejudice for subsequent resubmission, but forfeits the associated registration service fee. For cases described in (b), the applicant shall have up to 30 calendar days to reach agreement with the Agency on the final terms of the Agency-accepted label. If the applicant agrees to all of the terms of the accepted label as in (a), including upon resolution of differences in (b), the Agency shall provide an accepted final Agency-stamped label to the registrant within 2 business days following the registrant's written or electronic confirmation of agreement to the Agency.

[4](a) EPA-initiated amendments shall not be charged registration service fees. (b) Registrant-initiated fast-track amendments are to be completed within the timelines specified in FIFRA Section 3(c)(3)(B) and are not subject to registration service fees. (c) Registrant-initiated fast-track amendments handled by the Antimicrobials Division are to be completed within the timelines specified in FIFRA Section 3(h) and are not subject to registration service fees. (d) Registrant initiated amendments

submitted by notification under PR Notices, such as PR Notice 98–10, continue under PR Notice timelines and are not subject to registration service fees. (e) Submissions with data and requiring data review are subject to registration service fees.

[5] The applicant must identify the substantially similar product if opting to use cite-all or the selective method to support acute toxicity data requirements.

[6]Once a submission for a new product with public health organisms has been submitted and classified in either A540 or A541, additional organisms submitted for the same product before expiration of the first submission's original decision review time period will result in reclassification of both the original and subsequent submission into the appropriate new category based on the sum of the number or organisms in both submissions. A reclassification would result in a new PRIA start date and require additional fees to meet the fee of the new category.

[7]Once a submission for a label amendment with public health organisms has been submitted and classified in either A570 or A573, additional organisms submitted for the same product before expiration of the first submission's original decision review time period will result in reclassification of both the original and subsequent submission into the appropriate new category based on the sum of the number or organisms in both submissions. A reclassification would result in a new PRIA start date and require additional fees to meet the fee of the new category.